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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/033,543 12/27/2001 Joseph H. Contiliano ETH-1615 7364 27614 **EXAMINER** 7590 10/22/2004 RALPH W. SELITTO, JR. PHILOGENE, PEDRO C/O MCCARTER & ENGLISH, LLP PAPER NUMBER ART UNIT **GATEWAY CENTER FOUR** 100 MULBERRY STREET 3732 NEWARK, NJ 07102

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   |             |  |                         |       | ÅI |  |
|---|---|-------------|--|-------------------------|-------|----|--|
| Office Action Summary   |   | Application | on No.                                   | Applicant(s)            |       | 11 |  |
|   |   | 10/033,54   | 13                                       | CONTILIANO ET A         | L.    | /  |  |
|   |   | Examiner    |  | Art Unit                |       | -  |  |
|   |   | Pedro Ph    |  | 3732                    |       |    |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |   |             |  |                         |       |    |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |             |  |                         |       |    |  |
| Status  |   |             |  |                         |       |    |  |
| 1)⊠   | Responsive to communication(s) filed on 23 August 2004.   |             |  |                         |       |    |  |
| 2a)⊠  | This action is <b>FINAL</b> . 2b) ☐ This action is non-final.   |             |  |                         |       |    |  |
| 3)□   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |             |  |                         |       |    |  |
| Disposition of Claims   |   |             |  |                         |       |    |  |
| 5)⊠<br>6)⊠<br>7)□   | Claim(s) 1-22 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) 10-20 is/are allowed.  Claim(s) 1-9,21 and 22 is/are rejected.  Claim(s) is/are objected to.  Claim(s) are subject to restriction and/or election requirement. |             |  |                         |       |    |  |
| Application Papers  |   |             |  |                         |       |    |  |
| 9) The specification is objected to by the Examiner.  |   |             |  |                         |       |    |  |
| 10)[  | 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |             |  |                         |       |    |  |
|   | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |             |  |                         |       |    |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |             |  |                         |       |    |  |
| Priority under 35 U.S.C. § 119  |   |             |  |                         |       |    |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |             |  |                         |       |    |  |
| 2) Notic  | te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948)   |             | 4) Interview Summary Paper No(s)/Mail Da | ate                     |       |    |  |
| 3) 🖾 Infor<br>Pape  | mation Disclosure Statement(s) (PTO-1449 or PTO/SB/0<br>er No(s)/Mail Date 4/0/   | 08)         | 5) Notice of Informal F 6) Other:        | Patent Application (PTO | -152) |    |  |

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2-6,8,9,21,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhling et al. (5,169,400) in view of Rieger et al. (4,759,110).

With respect to claim 1, Muhling et al disclose a medical screw and driver system comprising: an elongated screw (1) having external threads (3) and an internal bore (5) extending through the screw at least a portion of the length of the screw, the screw being at least partially formed from a bio-absorbable material; as set forth in column 3, line 68, column 4, lines 1-5; an elongated driver (7,8) having a non-circular cross-section shape approximating the cross-sectional shape of the bore, as set forth in column 3, lines 65-68, column 4, lines 24-40, the driver being insertable into the bore and being matingly received therein to transfer rotational motion of the driver to the screw, the bore being capable of shrinking and molding itself to the driver as to exhibit a fitting-fit relative to the driver such that the cross-sectional shape of the bore is closely mated to the cross sectional shape of the driver, as set forth in column 3, lines 25-50, column 4, lines 32-40.

Although Muhling discloses a fitting relative to the driver, it is noted that muhling did not teach of a shrink-fit relative to the driver, and the driver may be withdrawn from

the bore without altering the cross sectional shape of the bore; as claimed by applicant. However, in a similar art, Rieger et al., evidence the use of a shrink-fit relative to the driver, and the driver may be withdrawn from the bore without altering the cross-sectional shape of the bore to provide a device that is reliable and avoids frequent breakdowns or failures.

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Therefore, given the teaching of Rieger et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the shrink-fit method and the removable driver, as taught by Rieger et al., in the device of Muhling to provide a device that is reliable and avoids frequent breakdowns or failures.

With respect to claims 2-6,9,21,22 Muhling et al discloses all the limitations, as set forth in column 4, lines 1-5,19-23,30-40; column 2, lines 39-47 and as best seen in FIGS: 1-12.

With respect to claim 8, it noted that the above combination of references discloses all the limitations, except for a ratio of a 15/85 blend of TCP/PLA, as claimed by applicant. However, applicant fails to establish the criticality of such a ratio. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach the optimum range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum range or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muhling et al. (5,169,400) in view of Rieger et al. (4,759,110) in view of Tunc (5,827,287).

With respect to claims 7,8, it is noted that the above combination of references did not teach of a screw having an additive to the composition thereof selected from the group consisting of bio-absorbable glass, as claimed by applicant. However, in a similar art, Tunc evidences the use of bio-absorbable glass to cause nucleation and to form a self-supporting member.

Therefore, given the teaching of Tunc, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the additive of Tunc in the composition of Muhling/Rieger et al., to cause nucleation and to form a self-supporting member.

## Allowable Subject Matter

Claims 10-20 are allowed.

### Response to Amendment

Applicant's arguments filed 8/23/04 have been fully considered but they are not persuasive. Applicant's added limitations in claim 1, only recite that the bore is capable of shrinking and molding. So, applicant is not positively claiming that the bore shrink and mold itself to the driver, only that it is capable of shrinking and molding to the driver. The device of Muhling et al is capable of shrinking and molding, as claimed by applicant. Further, applicant stated that the bore of the holder of Rieger'110 is enlarged upon heating so as to be greater than or equal to diameter of the piston. However, in claim 1, although applicant is claiming shrinking and molding, applicant is silent as to how the shrinking and the molding occurred. All that is needed in applicant claim 1, is

that the bore being capable of shrinking and molding, which the device of Muhling et al is capable of doing.

### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene October 20, 2004

> PEDRO PHILOGENE PRIMARY EXAMINER